

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 00N-0988]

4162-01-1F
DMB

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Certifier	SNRESE

Lilly Research Laboratories et al.; Withdrawal of Approval of 22
New Drug Applications and 36 Abbreviated New Drug Applications

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is withdrawing approval of 22 new drug applications (NDA's) and 36 abbreviated new drug applications (ANDA's). The holders of the applications notified the agency in writing that the drug products were no longer marketed and requested that the approval of the applications be withdrawn.

DATES: Effective [insert date 30 days after date of publication in the FEDERAL REGISTER].

FOR FURTHER INFORMATION CONTACT:

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Center for Drug Evaluation and Research (HFD-7),
Food and Drug Administration,
5600 Fishers Lane,
Rockville, MD 20857,
301-594-2041.

SUPPLEMENTARY INFORMATION: The holders of the applications listed in the table in this document have informed FDA that these

drug products are no longer marketed and have requested that FDA withdraw approval of the applications. The applicants have also, by their request, waived their opportunity for a hearing.

Application No.	Drug	Applicant
NDA 6-139	Surfacaine (cyclomethycaine).	Lilly Research Laboratories, Lilly Corporate Center, Indianapolis, IN 46285.
NDA 6-904	Terfonyl (trisulfapyrimidines) Tablets and Oral Suspension.	Bristol-Myers Squibb Co., P.O. Box 4000, Princeton, NJ 08543- 4000.
NDA 9-357	Rau-Sed (reserpine) Tablets.	Do.
NDA 9-523	Tyzine 0.1% (tetrahydrozoline HCl).	Pfizer, Inc., 235 East 42d St., New York, NY 10017- 5755.
NDA 9-941	Tyzine 0.05% (tetrahydrozoline HCl) Pediatric Nasal Drops.	Do.
NDA 10-520	Leritine (anileridine HCl) Injection.	Merck & Co., Inc., P.O. Box 4, BLA-20, West Point, PA 19486.
NDA 11-028	Hydeltrasol (prednisolone sodium phosphate) Sterile Ophthalmic Ointment, 0.25%.	Do.
NDA 11-178	Isuprel (isoproterenol hydrochloride) Mistometer.	Sanofi Winthrop, Inc., 90 Park Ave., New York, NY 10016- 1389.

Application No.	Drug	Applicant
NDA 11-602	Kenalog (triamcinolone acetone) Lotion.	Bristol-Myers Squibb Co.
NDA 12-335	Forhistal (dimethindene maleate) Tablets.	Novartis Pharmaceuticals Corp., 59 Route 10, East Hanover, NJ 07936-1080.
NDA 12-337	Forhistal (dimethindene maleate) Syrup.	Do.
NDA 12-338	Forhistal (dimethindene maleate) Pediatric Drops.	Do.
NDA 16-755	Diapid (Lypressin Nasal Solution USP) Nasal Spray.	Novartis Pharmaceuticals Corp.
NDA 16-990	Intal (Cromolyn Sodium for Inhalation USP) Capsules.	Rhone-Poulenc Rorer Pharmaceuticals, Inc., 500 Arcola Rd., P.O. Box 1200, Collegeville, PA 19426-0107.
NDA 17-605	Xylo-Pfan (Xylose USP) Powder.	Savage Laboratories, 60 Baylis Rd., Melville, NY 11747.
NDA 19-215	FEMSTAT (butoconazole nitrate) 2% Vaginal Cream (prescription).	Hoffmann-La Roche, Inc., 340 Kingsland St., Nutley, NJ 07110-1199.
NDA 19-359	FEMSTAT (butoconazole nitrate) Suppositories, 100 milligrams (mg).	Do.
NDA 20-750	Tilade (nedocromil sodium inhalation solution) Nebulizer Solution.	Rhone-Poulenc Rorer Pharmaceuticals, Inc.

Application No.	Drug	Applicant
NDA 50-128	Bicillin (penicillin G benzathine) Tablets.	Wyeth-Ayerst Laboratories, P.O. Box 8299, Philadelphia, PA 19101-8299.
NDA 50-306	GEOPEN (carbenicillin disodium) IM/IV.	Pfizer, Inc.
NDA 50-318	Kenalog-S Nasal Spray (neomycin sulfate-gramicidin and triamcinolone acetonide with phenylephrine).	Bristol-Myers Squibb Co.
NDA 50-518	Meclan (meclocycline sulfosalicylate) Cream, 1%.	Johnson & Johnson Consumer Companies, Inc., 199 Grandview Rd., Skillman, NJ 08558-9418.
ANDA 60-124	Strycin (streptomycin) Syrup.	Bristol-Myers Squibb Co.
ANDA 60-513	Streptomycin Sulfate Injection USP.	Do.
ANDA 60-933	Spectrocin (Neomycin Sulfate and Gramicidin Ointment USP).	Do.
ANDA 61-523	Achromycin (tetracycline HCl) Diagnostic Susceptibility Powder, 20 mg.	Wyeth-Ayerst Laboratories.
ANDA 61-605	ETHRIL (Erythromycin Stearate Tablets USP).	Bristol-Myers Squibb Co.
ANDA 62-224	Neomycin Sulfate Ointment USP.	Do.

Application No.	Drug	Applicant
ANDA 62-305	Pediamycin Suspension and Pediamycin Oral Drops (erythromycin ethylsuccinate for oral suspension).	Abbot Laboratories, 100 Abbott Park Rd., D-491, AP6B-1SW, Abbott Park, IL 60064-6108.
ANDA 62-306	Erythromycin Ethylsuccinate Tablets, 200 mg.	Do.
ANDA 62-334	Cefadroxil for Oral Suspension USP.	Apothecon, Inc., A Bristol-Myers Squibb Co., P.O. Box 4500, Princeton, NJ 08543-4500.
ANDA 62-390	Cifadroxil Tablets USP, 1 gram (g).	Do.
ANDA 62-818	Neomycin and Polymyxin B Sulfates and Gramicidin Ophthalmic Solution.	Fujisawa Healthcare, Inc., 3 Parkway North Center Deerfield, IL 60015-2548.
ANDA 64-026	Tobramycin Sulfate Injection USP, 40 mg/mL.	Apothecon, Inc.
ANDA 71-151	Bretylium Tosylate Injection.	AstraZeneca, 725 Chesterbrook Blvd., Wayne, PA 19087-5677.
ANDA 71-153	Bretylium Tosylate Injection.	Do.
ANDA 74-319	Naproxen Sodium Tablets USP.	Purepac Pharmaceutical Co., 200 Elmora Ave., Elizabeth, NJ 07207.
ANDA 74-360	Gemfibrozil Tablets USP, 600 mg.	Do.
ANDA 74-380	Metoprolol Tartrate Tablets USP, 50 mg and 100 mg.	Do.

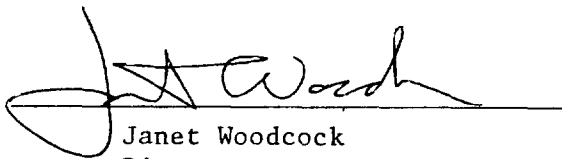
Application No.	Drug	Applicant
ANDA 74-658	Acyclovir Tablets USP, 400 and 800 mg.	Lek Pharmaceutical and Chemical Co. d.d., c/o Lek USA, Inc., 333 Sylvan Ave., Englewood Cliffs, NJ 07632.
ANDA 74-750	Acyclovir Capsules USP, 200 mg.	Do.
ANDA 75-516	Serecon Eye Drops (pheniramine maleate and naphazoline HCl ophthalmic solution), 0.315%/0.02675%.	Optikem International, Inc., c/o Medvice Consulting, Inc., 623 Glacier Dr., Grand Junction, CO 81503.
ANDA 80-321	Prednisone Tablets USP, 5 mg.	Vintage Pharmaceuticals, Inc., 3241 Woodpark Blvd. Charlotte, NC 28206.
ANDA 80-322	Prednisolone Tablets USP, 5 mg.	Do.
ANDA 80-860	Vitamin A Capsules USP	Bristol-Myers Squibb Co.
ANDA 83-807	Prednisolone Tablets USP, 20 mg.	Vintage Pharmaceuticals, Inc.
ANDA 84-627	Quinidine Sulfate Tablets USP, 200 mg.	Pharmavite Corp., P.O. Box 9606, Mission Hills, CA 91346-9606.
ANDA 85-147	Quinidine Sulfate Tablets USP, 200 mg.	Jones Pharma, Inc., 1945 Craig Rd., P.O. Box 46903, St. Louis, MO 63146.
ANDA 85-150	Diphenhydramine HCl Capsules USP, 50 mg.	Purepac Pharmaceutical Co.
ANDA 85-156	Diphenhydramine HCl Capsules USP, 25 mg.	Do.

Application No.	Drug	Applicant
ANDA 85-665	Sustaire (theophylline anhydrous) Tablets.	Pfizer, Inc.
ANDA 86-454	AMITID Tablets (Amitriptyline HCl Tablets USP).	Bristol-Myers Squibb Co.
ANDA 86-569	Theoclear L.A.-130 and Theoclear L.A.-260 (theophylline extended-release capsules, 130 mg and 260 mg).	Schwarz Pharma, Inc. 5600 West County Line Rd., Mequon, WI 53092.
ANDA 87-073	MD-76 (Diatrizoate Meglumine and Diatrizoate Sodium Injection USP, 66%/10%).	Mallinckrodt, Inc., 675 McDonnell Blvd., P.O. Box 5840, St. Louis, MO 63134.
ANDA 88-758	Butalbital, Acetaminophen, and Caffeine Capsules USP, 50 mg/325 mg/40 mg.	Mallinckrodt Chemical, Inc., P.O. Box P, 58 Pearl St., Hobart, NY 13788-0416.
ANDA 89-023	TRIAD (Butalbital, Acetaminophen, and Caffeine Capsules USP), 50 mg/325 mg/40 mg.	Do.
ANDA 89-102	FEMCET (Butalbital, Acetaminophen, and Caffeine Capsules USP), 50 mg/325 mg/40 mg.	Do.
ANDA 89-426	Dipyridamole Tablets USP, 50 mg.	Purepac Pharmaceutical Co.

Therefore, under section 505(e) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(e)) and under authority delegated to the Director, Center for Drug Evaluation and Research (21 CFR

5.82), approval of the applications listed in the table in this document, and all amendments and supplements thereto, is hereby withdrawn, effective [insert date 30 days after date of publication in the FEDERAL REGISTER].

Dated: 3/7/00
March 7, 2000



Janet Woodcock
Director
Center for Drug Evaluation and Research

CERTIFIED TO BE A TRUE COPY OF THE ORIGINAL.

